Food and Drug Administration
College Park, MD 20740

MAR 16 2004

Jonathan W. Emord, Esq.
Emord and Associates, P.C.
5282 Lyngate Court
Burke, VA 22015

      RE: Health Claim Petition – Calcium and kidney stones and/or urinary stones
           (Docket No. 2004Q-0102)

Dear Mr. Emord:

This letter acknowledges receipt on March 3, 2004 by the Food and Drug Administration
(FDA) of your letter dated March 2, 2004 regarding the various calcium health claim
petitions you submitted on November 25, 2003 on behalf of Marine Bio USA, Inc. We
understand that the petitioner has elected to have their health claim petitions reviewed
under the new process for qualified health claims rather than under the standard health
claim review process described in Section 403(r)(5)(D) of the Federal Food, Drug and
Cosmetic Act (21 U.S.C. § 343(r)(5)(D)). We will follow the interim procedures for
qualified health claims described in the FDA publication entitled "Consumer Health
Information for Better Nutrition Initiative" Task Force Final Report
(http://www.cfsan.fda.gov/~dms/nuttftoc.html).

Accordingly, today (March 16, 2004) we are filing your petition for qualified health
claims about the relationship between calcium and (1) kidney stones, (2) urinary stones,
and (3) kidney stones and urinary stones. The petition is posted at this web address
(http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm) and
we are requesting comment on it for 60 days. Interested persons may submit comments
until May 17, 2004. Within 225 days of the filing date we will notify you of our final
decision regarding the requested qualified health claims. We have calculated that date to
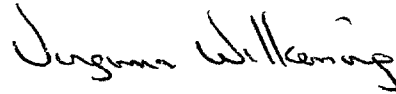be October 27, 2004.

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Please feel free to contact Ms. Nancy Crane at 301-436-1456 if you have any questions concerning this petition.

Sincerely yours,

Virginia Wilkening

for Laura M. Tarantino, Ph.D.
Acting Director
Office of Nutritional Products, Labeling
    and Dietary Supplements
Center for Food Safety
    and Applied Nutrition